

# ARIZONA BIOMEDICAL RESEARCH COMMISSION

## REQUEST FOR COMPETITIVE SEALED PROPOSALS RFP NO. FY08-200

### THE ARIZONA NON-EMBRYONIC STEM CELL REPOSITORY

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## **B. INTRODUCTION**

The Arizona Legislature has recently authorized appropriation from the State General Fund to the Arizona Biomedical Research Commission (“ABRC”) of \$1,000,000 for each Fiscal Year from 2007 to 2012 for the purpose of establishing “centralized public Arizona repositories of diverse types of human stem cells of non-embryonic origin for public use.” Accordingly, the ABRC is here requesting Competitive Sealed Proposals from individuals, organizations, corporations, and institutions, public or private, for the establishment of the Arizona Non-embryonic Stem Cell Repository (“ANeSCR”) – a much-needed resource for Arizona patients and an invaluable tool for Arizona researchers.

## **C. INSTRUCTIONS TO OFFERORS**

- C.1 Submission of Proposals.** One (1) original proposal and seven (7) copies must be received (not postmarked), in a sealed envelope or box clearly marked “PROPOSAL RFP No. FYO8-200” no later than 4:00 p.m. on February 4, 2008 at the:

Arizona Biomedical Research Commission  
15 South 15<sup>th</sup> Avenue, Suite 103-A  
Phoenix, Arizona 85007

No facsimiles, emails, or other forms of electronic submission will be accepted. Late proposals will not be accepted or considered.

- C.2 Form of Response.** Clip proposals together with binder clips. Do not submit bound or stapled proposals. Label the proposal with original signature “ORIGINAL” and place it on top. If your proposal contains original photographs or other materials that are necessary for the peer reviewers, you may mark three (3) of the seven (7) copies as “PEER REVIEWER COPY.” These three (3) copies shall be placed directly beneath the ORIGINAL.

Proposals shall be submitted on 8 ½ X 11 inch pages, single-spaced using standard type sizes of 10 point or larger for word-processed documents. Seven (7) copies of any attachments that cannot conform to the size requirements, or that rely upon color for effectiveness, must be provided.

Each section must be clearly labeled.

Place tables, charts, photos, and diagrams in their appropriate location in the text. Number and caption each.

Responses to Proposal Requirements in Section D must follow the order listed in Section D. Each subsection of the response must begin on a separate page and be labeled at the top.

**C.3 Confidentiality of Response.** Pursuant to the Arizona Administrative Code (A.A.C.) R2-7-103, Offerors may designate portions of proposals submitted under this RFP as proprietary and confidential.

**C.4 Arizona Procurement Code.** That section of the Arizona Procurement Code governing Competitive Sealed Proposals (A.R.S. § 41-2534) and the corresponding Arizona Administrative Rules (A.A.C. R2-7-C301 *et seq.*) are a part of this document as if fully set forth herein and shall govern as applicable.

**C.5 Vendor Registration.** The successful Offeror (the “Contractor”) must obtain a State Procurement Office (“SPO”) Vendor Number by completing a Vendor Registration Application prior to receiving any payments under the awarded Contract. Vendor Registration Application packets may be obtained from:

State Procurement Office  
Arizona Department of Administration  
100 North 15<sup>th</sup> Avenue, Suite 104  
Phoenix, Arizona 85007  
(602) 542-5511

**C.6 Timetable.**

Advertisements of Legal Notice will run the weeks of ....December 31, 2007 and January 7, 2008  
Deadline for Receipt of Written Requests for Technical Assistance .....January 11, 2008  
Deadline for Submission of Proposals .....February 4, 2008  
Proposal Opening .....February 5, 2008  
Proposed Contract Awarded under this RFP ..... July 1, 2008 to June 30, 2009

**C.7 Amendments to RFP.** Any and all amendments to this RFP shall be sent to all RFP recipients by first class mail. **Copies of amendments must be signed by the Offeror and returned with the proposal.**

**C.8 Cancellation of RFP.** ABRC reserves the right, at its complete discretion, to cancel this RFP in its entirety. In such event, all persons/organizations receiving the RFP will be notified by mail.

**C.9 Negotiations.** ABRC reserves the right, pursuant to A.A.C. R2-7-C314, to conduct negotiations with Offerors who submit proposals determined to have a reasonable chance of being selected.



## D. PROPOSAL REQUIREMENTS

The Arizona Non-embryonic Stem Cell Repository (“ANeSCR”) shall be a public, nonprofit repository of donated cord blood and other non-embryonic human stem cells, the purpose of which is to:

1. support proven therapies and provide services and products to patients who have life-threatening illnesses, need stem cell transplant, and may not have family-related donors;
2. promote medical and scientific advancement by collecting, preparing, storing, tracking, and providing access to, umbilical cord blood, nonembryonic stem cells, and other cellular products for investigators doing research into new therapies and other clinical applications;
3. encourage additional collaborative medical and scientific stem cell research in Arizona; and,
4. enrich the National Cord Blood Inventory (“NCBI”) through the addition of Hispanic, Native American, and other special population donations.

**Respondents to this RFP (“Offerors”) must demonstrate their commitment to this purpose, as well as their capability to plan, finance, develop, and continuously operate the ANeSCR in conformance with the terms, conditions, and requirements herein described. The requirements addressed in Section D constitute the minimum information required in response to this RFP.**

**D.1 Background of Offeror.** There are no restrictions on who may respond to this RFP, so long as they are qualified and prepared to meet the RFP/Contract terms and conditions herein described. Individuals, institutions (public and private), and corporations (profit and nonprofit) are all eligible. **Each Offeror, however, must provide sufficient identifying and background information on themselves or their organizations to enable ABRC to ascertain their suitability for possible contract award.**

**D.1.1 Financial Capability.** As discussed in detail in Section 4 of the “ABRC Contractual Funding Agreement” portion of this document (“Funding Agreement”), ABRC will disburse to the successful Offeror (“Contractor”) a total of \$5,000,000 over the period of 2008-2013 (“ABRC Funding Commitment”). As a condition of this disbursement, Contractor is required to provide Matching Funds on a 1:1 basis. Such Matching Funds may be any combination of Contractor’s own funds, donated funds, grant funds from other sources properly authorized for this purpose, and/or in-kind matches which may be accepted by ABRC when they are directly associated with ANeSCR requirements and offered for the disbursement period as required. Appropriate in-kind matching proposals may include

such things as: joint use of existing space, joint use of existing information systems and other equipment, and joint use of existing personnel. ABRC's annual disbursement in each of the five (5) years of this Contract shall match exactly the dollar (or in-kind dollar-equivalent) amount of Matching Funds provided by the contractor for each year, up to the total ABRC Funding Commitment. **Accordingly, each Offeror must provide both appropriate background financial information (either personal or organizational) and a "Matching Funds Plan" with sufficient detail and specificity to enable ABRC to evaluate Offeror's financial capability to successfully develop and operate ANeSCR. In addition, Offeror must provide the signed "Offeror's Attestation and Commitment Statement" described in Section D.6.**

**D.2 Legal Structure of ANeSCR.** As discussed in detail in Sections 3.2.1 - 3.2.4 of the Funding Agreement, the successful Offeror ("Contractor") is required either to (1) incorporate a separate Arizona nonprofit corporation or, as an alternative **if** Offeror/Contractor is already a tax-exempt Arizona nonprofit corporation, (2) form a wholly-owned L.L.C., name it the "Arizona Non-embryonic Stem Cell Repository" (ANeSCR), apply for 501(c)(3) tax-exemption (unless such tax-exemption can be "passed through" to the wholly-owned L.L.C.), take all steps necessary to allow ANeSCR to succeed to Contractor's interest in the awarded contract, and otherwise meet the ongoing organizational and other requirements for ANeSCR as described throughout this document. **Accordingly, each Offeror must provide the signed "Offeror's Attestation and Commitment Statement" described in Section D.6 that, among other things, affirms their willingness to meet, and capability of meeting, these requirements.**

**D.3 Offeror Work Plan.** Each Offeror must provide a Work Plan that gives a detailed description of the scope of, and manner by which the Offeror intends to provide, the specific financing, Services, and Materials necessary to meet the objectives and fulfill the requirements of this RFP for establishment, development, and ongoing operation of ANeSCR. At a minimum, the Work Plan shall address each of the following:

1. Capital Requirements (including space, equipment, and furnishings)
2. Staffing (managerial, administrative, and clinical – including brief position descriptions and qualification summaries)
3. Accounting and Reporting Systems (particularly including Cost Accounting capability – see Section 3.2.6 re Required Pricing Structure)

4. Information Systems (include description of intended capability)  
[Note: ABRC wishes ANeSCR to have a data base that is readily accessible to all authorized users. In addition, ABRC wishes to foster the creation of an information network of tissue banks. Accordingly, ANeSCR may be required by ABRC to incorporate additional software into their system or otherwise establish a means of exporting and importing repository data to and from a central data system. The system must also be capable of (1) interfacing with the National Cord Blood Inventory (“NCBI”) and (2) “annotating” the donated biospecimens as discussed in Section D.3.3.]
5. Data Collection Strategies and Mechanisms
6. Policies and Procedures
7. Quality Control and Improvement Strategies and Mechanisms (including quantifiable performance and efficiency metrics)
8. Mechanisms to Maintain Regulatory Compliance, Accreditations, and Professional Affiliations (see Sections D.3.1, D.3.2, 3.2.5.1, and 3.2.5.2.)
9. Mechanisms to Ensure Compliance with ABRC Contract
10. Intended Accreditations (see Section 3.2.5.2)
11. Intended Affiliations and/or Collaborations
12. Program Implementation Timeline (including specific milestones)
13. Disaster Recovery and Pandemic Performance Plan (see Section 15.4 re Pandemic Contractual Performance)

**D.3.1 Regulation: Federal Registration, Listing, and Licensure.** The U.S. Food and Drug Administration (“FDA”) is responsible for ensuring the safety of our nation's blood supply, including cord blood. Within the FDA, the Center for Biologics Evaluation and Research (“CBER”) regulates the collection of blood and blood components used for transfusion or for the manufacture of pharmaceuticals derived from blood and blood components, such as clotting factors, and establishes standards for the products themselves. CBER also regulates related products such as cell separation devices, blood collection containers, and HIV screening tests that are used to prepare blood products or to ensure the safety of the blood supply. CBER develops and enforces quality

standards, inspects blood establishments, and monitors reports of errors, accidents, and adverse clinical events. CBER works closely with other parts of the Public Health Service to identify and respond to potential threats to blood safety, to develop safety and technical standards, to monitor blood supplies, and to help industry promote an adequate supply of blood and blood products. FDA has significantly increased its oversight of the blood industry. The agency inspects all blood facilities at least every two years, and "problem" facilities are inspected more often. Blood establishments are now held to quality standards comparable to those expected of pharmaceutical manufacturers.

In December 2006, CBER published a draft document entitled "Guidance for Industry: Minimally Manipulated, Unrelated, Allogenic Placental/Umbilical Cord Blood Intended for Hematopoietic Reconstitution in Patients with Hematological Malignancies." (For a copy of the entire guidance, go to: [www.fda.gov/cber/gdlns/cordbld.pdf](http://www.fda.gov/cber/gdlns/cordbld.pdf).)

**Each Offeror's Work Plan must demonstrate the Offeror's familiarity with the Federal Registration, Listing, and Licensure requirements applicable to ANeSCR as explained in the CBER draft industry guidance, and describe in detail how the Work Plan incorporates necessary steps to initially meet or exceed, and subsequently maintain compliance with, all applicable regulatory requirements. Specifically, as indicated in Section 3.2.5.1: ANeSCR shall at all times operate in strict compliance with CBER's then-current registration, listing, and licensure requirements governing both "human cells, tissues, and cellular and tissue-based products" ("HCT/Ps") and "hematopoietic progenitor cells, cord" ("HPC-Cs"), including all applicable Current Good Tissue Practice ("CGTP") regulations and Current Good Manufacturing Practice ("CGMP") regulations.**

- D.3.2** Accreditation: Participation in National Cord Blood Inventory. On December 20, 2005, the Stem Cell Therapeutic Act of 2005 was enacted as Public Law 109-129. The Act authorizes the establishment of the National Cord Blood Inventory ("NCBI") and the C.W. Bill Young Cell Transplantation Program as the successor to the National Bone Marrow Donor Registry. The NCBI is to be a high quality, genetically diverse inventory of cord blood units for patients who need a blood stem cell transplant and who lack an available related donor. The cord blood units in the NCBI will be made available for transplantation through the C.W. Bill Young Cell Transplantation Program. Cord blood banks collecting and maintaining units for the NCBI must meet the statutory definition of a qualified cord blood bank, which includes a

requirement that cord blood banks be accredited by an accreditation entity recognized by the Secretary of the U.S. Department of Health and Human Services for this purpose.

Public Law 109-129 requires the Secretary to recognize one or more cord blood accreditation entities for the accreditation of cord blood banks participating in the collection and maintenance of umbilical cord blood units for the NCBI. The Health Resources & Services Administration (“HRSA”), Healthcare Systems Bureau (HSB), Division of Transplantation (DoT) is in the process of information-gathering to assist in the determination of which cord blood bank accreditation program(s) to recognize on an interim basis for the initial cycle of funding for the NCBI.

**Since one of the primary objectives of the ANeSCR is to enrich the NCBI through the addition of Hispanic, Native American, and other special population donations, each Offeror shall demonstrate their familiarity with the activities of the NCBI and describe the steps they will take to ensure ANeSCR’s ability to participate with NCBI as a qualified cord blood bank. Such steps shall include, as appropriate, obtaining accreditation and/or certification from one or more of the following: the American Association of Blood Banks (“AABB”), the Foundation for the Accreditation of Cellular Therapy (“FACT”), the American Association of Tissue Banks (“AATB”), and/or the American Society for Histocompatibility and Immunogenetics (“ASHI”). In addition, each Offeror should describe any intended professional affiliations, such as with the American Society for Blood and Marrow Transplantation (“ASBMT”) and/or the American International Society for Cellular Therapy (“AISCT”).**

**D.3.3** Requirements for Secondary Research. “Secondary research” means any research that is conducted on data or tissue (i.e., an “asset”) that already exists from a primary source. Any third-party researcher accessing ANeSCR’s donated biospecimens and/or ANeSCR’s computerized “annotations” (i.e., computerized linkages to data describing such characteristics of the biospecimen as the source individual’s zip code of residence, age, gender, race/ethnicity, diagnosis, date of disease onset, treatment, outcome, etc.) on such biospecimens is necessarily doing secondary research, since they are not themselves obtaining the biospecimen or the annotation data directly from the source individual. Accordingly, in order to maintain and maximize the utility and value of its biospecimen inventory for secondary research, ANeSCR will need to develop mechanisms to meet three (3) particular requirements: (1) ensuring that each donated biospecimen and its associated annotation data have been obtained

with consents and/or authorizations from the source individual that are legally sufficient under applicable state and federal law (e.g., the Common Rule, the HIPAA Privacy Standards, etc.) to permit all foreseeable secondary research uses; (2) ensuring that all necessary and appropriate annotation data is obtained on each donated biospecimen; and, (3) acting as the “honest broker” or “gatekeeper” of all “Protected Health Information” (“PHI”) within the biospecimen annotation data base, providing to secondary researchers only (i) de-identified data not requiring the source individual’s consent/authorization (when such de-identified data is sufficient), or (ii) PHI data for which legally sufficient consent/authorizations have been obtained (when such PHI is necessary for the research purpose). **Each Offeror must describe the ways and means through which it will ensure that ANeSCR meets these requirements.**

**D.4 Offeror Preliminary 5-Year Budget. Each Offeror must provide a Preliminary 5-Year Budget based upon the Work Plan described in D.3 above (see Section 3.1.5).**

**D.5 Offeror Sustainability Plan. The overriding intent of the Legislature’s appropriation, and the ABRC’s solicitation through this RFP, is to select an Offeror who will be able to develop ANeSCR into a financially independent, fully functional public repository at the end of ABRC’s Funding Commitment. Accordingly, each Offeror must provide a description of the steps it will take to ensure the long-term operational and financial sustainability of the ANeSCR.**

**D.6 Offeror’s Attestation and Commitment Statement. Each Offeror must make the following attestations and commitment by dating, signing, notarizing, and returning as part of their proposal Attachment 1 to this document.**

1. Offeror asserts that they have fully read the entirety of this document, including the RFP and Funding Agreement portions, and completely understand all of the terms and conditions to which they will be legally bound if awarded a contract under this RFP.
2. Offeror asserts that submission of their proposal did not include collusion or other anti-competitive practices.
3. Offeror asserts that they have not been debarred, suspended, or otherwise lawfully prohibited from participating in any public procurement activity, including but not limited to being disapproved as a subcontractor of any public procurement unit or other governmental body.

4. Offeror hereby commits, if awarded a contract under this RFP, to: incorporate a separate Arizona nonprofit corporation (or form a wholly-owned nonprofit L.L.C. if Offeror/Contractor is an existing Arizona nonprofit corporation), name it the “Arizona Non-embryonic Stem Cell Repository” (ANeSCR), apply for 501(c)(3) tax-exemption (unless such tax-exemption can be “passed through” to a wholly-owned L.L.C. by an existing Arizona nonprofit corporation), take all steps necessary to allow ANeSCR to succeed to Contractor’s interest in the awarded contract, and otherwise meet the ongoing organizational and other requirements for ANeSCR as described throughout this document.
5. Offeror asserts that they have had full opportunity to review and discuss the entirety of this document and its requirements with counsel of their choosing.

## **E. CONTRACT AWARD**

### **E.1 ABRC Review Process.**

#### ***First level of review:* STAFF REVIEW**

All proposals are reviewed for compliance with, and responsiveness to, this RFP. Proposals shall be eliminated from further review if determined to be materially incomplete according to the instructions and requirements set forth herein.

#### ***Second level of review:* PEER REVIEW (EXTERNAL)**

Technical evaluations are obtained from out-of-state peer reviewers. These reviewers are scientific, health, medical, and business experts recruited in accordance with the requirements of this RFP. A site visiting team consisting of experts and members of the Commission may visit each Offeror as a part of the proposal review and scoring process. Offerors may be asked to present their backgrounds to an evaluation team and answer questions about their proposals.

#### ***Third level of review:* COMMISSION REVIEW**

After receiving the external scientific peer review, the ABRC will meet and make a decision concerning the final contract award.

### **E.2 ABRC Evaluation Criteria. The following factors and criteria, **in the listed order of relative importance**, shall be used to evaluate proposals submitted in response to this RFP.**

1. The Offeror's commitment to the stated purpose of the ANeSCR and their demonstrated capability to plan, finance, develop, and continuously operate same in conformance with the terms, conditions, and requirements herein described.
2. The assessed competency, credibility, and sufficiency of Offeror's submitted Work Plan.
3. The assessed competency, credibility, and sufficiency of Offeror's Preliminary 5-Year Budget and submitted Sustainability Plan (see D.5).
4. The overall conformance of Offeror's proposal with all requirements of this Contract.

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**ABRC CONTRACTUAL FUNDING AGREEMENT  
RFP NO. FY08-200**

**THE ARIZONA NON-EMBRYONIC STEM CELL REPOSITORY**

**THIS CONTRACTUAL FUNDING AGREEMENT** is entered into by and between the ARIZONA BIOMEDICAL RESEARCH COMMISSION (“ABRC”) and \_\_\_\_\_,  
 (“Contractor”).

**RECITALS**

I. The Arizona Legislature has determined that establishment of centralized public Arizona repositories of diverse types of human stem cells of non-embryonic origin for public use is in the best interest of the citizens of Arizona.

II. In furtherance of this objective, the Legislature has passed Laws 2007, Chapter 263, Section 42, providing ABRC with an appropriation of \$1,000,000 for each Fiscal Year from 2007 to 2012 for this purpose. (Monies from these appropriations are exempt from the provisions of A.R.S. § 35-190 relating to lapsing of appropriations.)

III. The Legislature has mandated that ABRC establish a competitive request for proposal process to establish the repositories.

IV. Contractor has been selected by ABRC to develop the Arizona Non-embryonic Stem Cell Repository (“ANeSCR”) following a “Request for Competitive Sealed Proposals” process conducted in accordance with A.R.S. § 41-2534 and A.A.C. R2-7-C301 *et seq.*

NOW, THEREFORE, in consideration of the provisions set forth herein, the Parties agree as follows:

**AGREEMENTS**

**1. DEFINITIONS**

As used throughout this document, the following terms shall have the meanings set forth:

1.1 “**ABRC**” means the Arizona Biomedical Research Commission or any

successor in interest, or any renamed or reorganized instrumentality of the State of Arizona that performs the functions of the current ABRC relative to this Agreement.

- 1.2 “**ABRC Funding Commitment**” means the funding set forth in Section 4.
- 1.3 “**Accounting Procedures Manual**” means Contractor/ANeSCR’s written statement of procedures to be followed by Contractor/ANeSCR in connection with all reporting and monitoring of its expenditures and financial statements as required under this Contract.
- 1.4 “**Allowable Expenditures**” means expenditures permitted pursuant to Section 5.
- 1.5 “**ANeSCR**” means the Arizona Non-embryonic Stem Cell Repository
- 1.6 “**Annual Audit**” means the financial statements required by Subsection 3.2.8.1.
- 1.7 “**Attachment**” means any item the Offeror is required or chooses to submit as part of their response to this RFP.
- 1.8 “**Chairman**” means the Chairman of ABRC or duly authorized representative.
- 1.9 “**Contract**” means this, and related documents, encompassing RFP No. FY08-200, including:
- the Request For Competitive Sealed Proposal portion of this document (“RFP”) and all of Contractor’s written responses and Attachments thereto, specifically including “Offeror’s Attestation and Commitment Statement.”
  - the ABRC Contractual Funding Agreement portion of this document (“Funding Agreement”) when signed by both Parties.
  - any and all Contract Amendments.
- 1.10 “**Contract Amendment**” means a written document signed by both Parties to effect an agreed-upon change to this Contract.
- 1.11 “**Contractor**” means \_\_\_\_\_, to be succeeded pursuant to Subsection 3.2.1.1 hereof in all interests, rights, and obligations under this Contract by ANeSCR immediately upon ANeSCR attaining separate legal status.

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**NOTE: “Offeror” becomes “Contractor” upon the Effective Date of this Contract. “Contractor,” in turn, becomes “ANeSCR” once ANeSCR attains separate legal status (as discussed in Section 3.2.1), except for Contractor’s separate and continuing duty to meet its Matching Funds obligation hereunder.**

**Whenever in this document reference is made to “Contractor/ANeSCR,” the reference shall variously be to “Contractor,” “ANeSCR,” or both, as the context requires.**

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- 1.12 **“Contract Year”** means each successive year following the Effective Date of this Contract.
- 1.13 **“Days”** means calendar days, unless otherwise specified.
- 1.14 **“Effective Date”** is defined in Subsection 2.2.
- 1.15 **“Event of Default”** is defined in Subsection 14.1.
- 1.16 **“Executive Director”** means the person designated to represent ABRC as the program administrator of this Contract.
- 1.17 **“Expenditure Reports”** means the Annual Expenditure Reports required by Subsection 3.2.8.2 and the Quarterly Expenditure Reports required by Subsection 3.2.8.3.
- 1.18 **“Fiscal Year”** means the period beginning with July 1 and ending June 30.
- 1.19 **“Gratuity”** means a payment, loan, subscription, advance, deposit of money, services, or anything of more than nominal value, present or promised, unless consideration of substantially equal or greater value is received.
- 1.20 **“Hardship Cases”** means persons determined eligible for services covered by the Arizona Health Care Cost Containment System (“AHCCCS”).
- 1.21 **“Letter Notice of Contract Award”** means the letter that ABRC will send the successful Offeror advising that they have been selected to receive the contract award under this RFP.
- 1.22 **“Matching Funds”** means Contractor’s required 1:1 match to ABRC Funding, as defined in Section 4. In-kind matches may be accepted by ABRC when they are directly associated with ANeSCR requirements and

offered for the disbursement period as required. Appropriate in-kind matching proposals may include such things as: joint use of existing space, joint use of existing information systems and other equipment, and joint use of existing personnel.

- 1.23 “**Materials**” means all property, including equipment, supplies, printing, insurance, and leases of property, but does not include land, a permanent interest in land, or other real property.
- 1.24 “**Offeror**” means the person or organization responding to this RFP, intending to be bound as “Contractor/ANeSCR” if awarded this Contract.
- 1.25 “**Parties**” means the ABRC and Contractor/ANeSCR.
- 1.26 “**Services**” means the furnishing of labor, time, or effort by a contractor or a subcontractor which does not involve the delivery of a specific end product other than required reports and performance.
- 1.27 “**Shall**” means what is mandatory.
- 1.28 “**Special Population**” means subgroups of the general population, including but not limited to Native Americans and/or Hispanic/Latino populations.
- 1.29 “**State**” means the State of Arizona, including ABRC, and shall not, for purposes of this Contract, include Contractor/ANeSCR.
- 1.30 “**Subcontract**” means any contract between Contractor/ANeSCR and a third-party to provide, or be accountable for providing, any material part of the performance which Contractor/ANeSCR has itself contracted with ABRC to perform or provide under this Contract.
- 1.30 “**Work Plan**” means a detailed description of the scope and manner by which the Offeror intends to provide the specific financing, Services, and Materials necessary to meet the objectives, and fulfill the requirements, of this Contract for establishment, development, and ongoing operation of ANeSCR.

## **2. PURPOSE, EFFECTIVE DATE, TERM & GENERAL REQUIREMENTS**

- 2.1 Purpose. This Contract provides for the disbursement of funds by ABRC to Contractor/ANeSCR under applicable law and the terms and conditions set forth herein. Disbursements shall be made only to Contractor/ANeSCR and not to any creditor of Contractor/ANeSCR.
- 2.2 Effective Date. This Contract shall become effective on the date the

ABRC Contractual Funding Agreement portion of this document is signed by both Parties in the space provided on the last page of this document. Any Contract Amendments shall become effective on the date executed by the Parties, or at a later date as specified therein.

- 2.3 Term. The term of this Contract shall be from the Effective Date until the date of submission by Contractor/ANeSCR of the final Expenditure Reports, Annual Audit, and Annual Report due in 2013.
- 2.4 No Exemption. This Agreement sets forth the material powers ABRC expects to exercise respecting Contractor/ANeSCR and the material obligations to ABRC that Contractor/ANeSCR is expected to perform hereunder. However, ABRC does not, by this Contract, purport to expand or to limit any duty or power conferred upon it by law, or limit any provision of applicable law. Contractor/ANeSCR must comply with all applicable federal, State, and local regulations, codes, and laws affecting its operations. Nothing in this Contract constitutes an exemption or grant of a variance from applicable codes and laws.
- 2.5 Relationship of the Parties. Contractor/ANeSCR is an independent contractor in the performance of all activities, functions, duties, and obligations under this Contract. Contractor/ANeSCR and ABRC are not, and shall not be considered to be, joint venturers, partners, or agents of each other. Contractor/ANeSCR's officers, employees, agents and subcontractors shall not be considered to be officers, employees, or agents of ABRC. ABRC and Contractor/ANeSCR hereby agree not to represent to anyone that they are agents of one another or have authority to act on behalf of one another.
- 2.6 Permits. Contractor/ANeSCR, unless otherwise exempt by law, shall obtain and maintain all licenses, permits, and authority necessary to do business and perform its covenants and obligations under this Contract.
- 2.7 Lack of Interest. No individual employed by the State shall have a substantial interest in this Contract or receive a substantial benefit that may arise therefrom.
- 2.8 Financial Reporting, Record Keeping, and Audit Requirements. Contractor/ANeSCR shall comply with the reporting, record keeping, and audit requirements set forth in Subsections 4, 5, 6, 9, and elsewhere in this Contract.

### 3. REPRESENTATIONS, WARRANTIES, AND COVENANTS

- 3.1 Warranties of Offeror, Contractor, and ANeSCR. All representations, warranties, and covenants made by Offeror, Contractor, and ANeSCR under this Contract (except for Sections 3.2.1(2), 3.2.8 [and

**all subsections thereof], 3.2.9 [and all subsections thereof], 3.2.10, 3.2.12, and 5.1.1) shall survive the expiration or termination hereof.** In addition, the Parties acknowledge that, pursuant to A.R.S. § 12-510, except as provided in A.R.S. § 12-529, the State is not subject to or barred by any limitations of actions prescribed in A.R.S. Title 12, Chapter 5.

**3.1.1** Authority of Offeror. Offeror represents and warrants that it has full power and authority to enter into this Contract, and the execution, delivery, and consummation of this Contract by Offeror have been duly authorized by all necessary action. **Accurate copies of the current articles of incorporation and bylaws (or other like organizational documents) of Offeror (if any) have been provided to ABRC.**

**3.1.2** No Conflict. Offeror represents and warrants that the execution, delivery, and consummation of this Contract by Offeror is not prohibited by, and does not conflict with, any other contracts or instruments to which Offeror is a party or is otherwise subject.

**3.1.3** Compliance With Laws; Judgments. Offeror represents and warrants that it has received no notice, as of the Effective Date of this Contract, asserting any noncompliance in any material respect by Offeror with applicable statutes, rules, or regulations of the United States of America, the State of Arizona, the City of Phoenix, or of any other state, municipality, or agency having jurisdiction over, or with respect to, the transactions contemplated in and by this Contract, and Offeror is not in default with respect to any judgment, order, injunction, or decree of any court, administrative agency, or other governmental authority in any respect material to the transactions contemplated in and by this Contract.

**3.1.4** Warranty Against Payment of Consideration for Contract. Offeror represents and warrants that it has not paid or given, and will not pay or give, any third person any money or other consideration for obtaining this Contract, other than normal costs of conducting business and costs of professional services such as consultants, engineers, realtors, and attorneys.

**3.1.5** Preliminary 5-Year Budget. Offeror represents and warrants that its governing authority (if any) has approved a preliminary 5-year budget for the establishment and operation of ANeSCR under this Contract (“Preliminary 5-Year Budget”), **and same has been provided to ABRC.**

**3.2** Contractor/ANeSCR Covenants. **In consideration for ABRC Funding, and as a conditional requirement for continued disbursements by**

**ABRC**, in addition to the other provisions of this Contract, Contractor/ANeSCR expressly covenants and agrees to comply with the terms and conditions set forth in this Subsection 3.2.

**3.2.1**     Organization. At least one hundred twenty (120) Days prior to the first day of repository operations, Contractor shall incorporate a nonprofit corporation duly organized and validly existing under the laws of the State of Arizona (or form a wholly-owned nonprofit L.L.C. if Offeror/Contractor is an existing Arizona nonprofit corporation), and name it the “Arizona Non-embryonic Stem Cell Repository” (“ANeSCR”). The Articles of Incorporation of ANeSCR (or Articles of Organization, if an L.L.C.) shall at all times provide:

1. that the purpose of the corporation, under A.R.S. § 10-3301 *et seq.*, as amended, (or of the L.L.C., under § 29-632(B), as amended), is to establish and operate a public, nonprofit repository of donated cord blood and other non-embryonic human stem cells, the purpose of which is to:
  - (i) support proven therapies and provide services and products to patients who have life-threatening illnesses, need stem cell transplant, and may not have family-related donors;
  - (ii) promote medical and scientific advancement by collecting, preparing, storing, tracking, and providing access to, umbilical cord blood, non-embryonic stem cells, and other cellular products for investigators doing research into new therapies and other clinical applications;
  - (iii) encourage additional collaborative medical and scientific stem cell research in Arizona by academic, healthcare, and biomedical research organizations;
  - (iv) enrich the National Cord Blood Inventory (NCBI) through the addition of Hispanic, Native American, and other special population donations; and,
  - (v) other similar activities consistent therewith;
2. that the board of directors (or the managers/members, if an L.L.C.) shall always include one full, voting member (or rotating designee) named by the Arizona

Biomedical Research Commission (ABRC), or its successor; and,

3. that the Articles of Incorporation of ANeSCR (or Articles of Organization, if an L.L.C.) shall at all times provide that, upon the dissolution of the Corporation (or L.L.C.), the Board of Directors (or Members/Managers of the L.L.C.) shall, after paying or making provision for the payment of all of the liabilities of the Corporation (or L.L.C.), distribute all of the assets of the Corporation (or L.L.C.) exclusively for the purposes of the Corporation (or L.L.C.) as the Board of Directors (or Members/Managers, if an L.L.C.) deems appropriate, except for the inventory of donated cord blood biospecimens and all associated “annotation data” (see Section D.3.3), the ownership of which shall be transferred to ABRC or its designee. The dissolution of the Corporation (or L.L.C.) shall be effected so as not to cause any tax to be imposed under Section 507(a) of the Internal Revenue Code of 1986, as amended (or the corresponding provision of any future United States Internal Revenue Law). In no event shall the assets of the Corporation (or L.L.C.) be distributed to any Director or Officer of the Corporation (or Member/Manager/Officer of the L.L.C.) or any private individual.

**3.2.1.1 ANeSCR Successor in Interest to Contractor.**

Contractor acknowledges that the intent of this Contract is to have ANeSCR, immediately upon attaining separate legal entity status, succeed to the entirety of Contractor’s interest in this Contract (**except for Contractor’s Matching Funds requirement under Sections 1.22 and 4, which shall remain Contractor’s separate continuing obligation**), and Contractor irrevocably agrees to such succession and further agrees to take any and all steps necessary to effect such succession.

- 3.2.2 ABRC Approval of Organizational Documents.** Contractor shall provide, for ABRC’s review and written approval, the Articles of Incorporation (or Articles of Organization, if an L.L.C.) described in Section 3.2.1 prior to filing with the Arizona Corporation Commission. In addition, Contractor shall also provide, for ABRC’s review and written approval, the corresponding Bylaws (or Operating Agreement, if an L.L.C.) of ANeSCR prior to their adoption by the entity’s governing



authority.

**3.2.3** Tax Exempt Status. Contractor/ANeSCR shall use best efforts to immediately qualify ANeSCR for federal income tax exemption under Section 501(c)(3) of the United States Internal Revenue Code. (Unless such tax-exemption can be “passed through” to a wholly-owned L.L.C. by an existing Arizona nonprofit corporation). Contractor/ANeSCR shall provide ABRC with a copy of the 501(c)(3) determination letter within ten (10) business days after receipt. ANeSCR shall not pay compensation that constitutes more than incidental private benefit, or constitutes private inurement, to any person, or engage in any transaction involving an excess economic benefit to a disqualified person within the meaning of I.R.S. § 4958 and the regulations thereunder.

**3.2.4** No Restructuring. ANeSCR shall remain so incorporated (or formed, if an L.L.C.), named, and tax-exempt in perpetuity, unless and until dissolved. Any dissolution of ANeSCR, and/or any amendments to or restatement of its Articles of Incorporation (or Articles of Organization, if an L.L.C.), shall require the written approval of ABRC, or its successor.

**3.2.5** General Compliance with Applicable Laws. The Materials and Services supplied under this Contract shall at all times comply with all applicable federal, State, and local laws and Contractor/ANeSCR shall maintain all necessary licenses and permits required by all applicable jurisdictions.

**3.2.5.1** Required Registration, Listing, and Licensure. ANeSCR shall at all times operate in strict compliance with the Center for Biologics Evaluation and Research’s (CBER’s) **then-current registration, listing, and licensure** requirements governing both “human cells, tissues, and cellular and tissue-based products” (“**HCT/Ps**”) and “hematopoietic progenitor cells, cord” (“**HPC-Cs**”), specifically including all applicable Current Good Tissue Practice (“**CGTP**”) regulations and Current Good Manufacturing Practice (“**CGMP**”) regulations.

**3.2.5.2** Required Accreditations. ANeSCR shall at all times maintain whatever accreditation is necessary for ANeSCR to be recognized by the Secretary of the U.S. Department of Health and Human Services as a cord blood bank qualified to participate in the National Cord Blood Inventory (NCBI). ANeSCR shall accordingly obtain and maintain its accreditation by one or more appropriate accrediting bodies, including but not limited

to: the American Association of Blood Banks (AABB), the Foundation for the Accreditation of Cellular Therapy (FACT), the American Association of Tissue Banks (AATB), and/or the American Society for Histocompatibility and Immunogenetics (ASHI). In addition, ANeSCR shall establish and maintain such professional affiliations as are deemed appropriate for its business, including but not limited to such professional organizations as the American Society for Blood and Marrow Transplantation (ASBMT) and/or the American International Society for Cellular Therapy (AISCT).

- 3.2.6** Required Pricing Structure. ANeSCR shall develop an initial pricing structure to be applied to both its transplant products and services and to its research materials. The structure shall be tiered as follows:

**AZ Special Population/Hardship Cases: priced at unit cost + % markup**

**AZ patients and researchers: priced at unit cost + ↑ % markup**

**Non-AZ patients and researchers: priced at unit cost + ↑↑ % markup**

ANeSCR's initial pricing structure shall be submitted to ABRC for review and approval. Thereafter, the pricing structure may be amended as deemed appropriate by ANeSCR's board of directors (manager/members), except that at no time shall any product, service, or material be sold at a price equal to or below its unit cost.

- 3.2.7** Accounting System and Accounting Procedures Manual. Contractor/ANeSCR will provide to ABRC an accurate, current copy of the draft Accounting Procedures Manual to be used by ANeSCR, and will provide ABRC with an accurate, current copy of the Accounting Procedures Manual (a) promptly after it has been finalized and (b) each year with the Annual Report delivered pursuant to Subsection 3.2.8.4 (unless ANeSCR notifies ABRC in writing that there has been no change in the Accounting Procedures Manual since the version last delivered to ABRC). ANeSCR will also notify ABRC of, and make available to ABRC upon request, all material changes to the Accounting Procedures Manual promptly after adoption of any such change. ANeSCR shall comply with the Accounting Procedures Manual with respect to all reporting and monitoring of financial statements and expenditures required under this Agreement. Consistent with the requirements of A.R.S. § 35-181.03 and regulations thereunder, ANeSCR shall maintain a system of accounting that reflects the application of generally

accepted accounting principles (“GAAP”), consistently applied, or in accordance with federal single audit regulations. Contractor/ANeSCR shall also maintain a cost accounting capability sufficient to ensure ANeSCR’s ability to comply with the three-tiered pricing structure required of ANeSCR under Subsection 3.2.6.

**3.2.8** Reporting Requirements. As a condition to disbursement under Section 4, Contractor/ANeSCR shall furnish to ABRC the following:

**3.2.8.1** Annual Audit. Within ninety (90) Days after the close of each Fiscal Year of the State of Arizona (by October 1), ANeSCR shall deliver to ABRC financial statements of ANeSCR for the 12 months ended the immediately preceding June 30 (“Annual Audit”), including a balance sheet and statement of income and expenses, which are audited by a nationally recognized firm of independent certified public accountants and are either (i) prepared in accordance with federal single audit regulations or (ii) prepared in accordance with generally accepted accounting principles with an unqualified opinion as to the fairness of the statements from such firm.

**3.2.8.2** Annual Expenditure Report. Within ninety (90) Days after the close of each Fiscal Year of the State of Arizona (by October 1), ANeSCR shall deliver to ABRC a report (“Annual Expenditure Report”) meeting the requirements of Subsection 3.2.9 of expenditures by ANeSCR during the 12 months ended the immediately preceding June 30, of all ABRC Funding previously disbursed by ABRC to ANeSCR in such period.

**3.2.8.3** Quarterly Expenditure Reports. Within thirty (30) Days after the close of each of the first three (3) fiscal quarters of the Fiscal Year of the State of Arizona for Fiscal Years 2007-2008 through 2012-2013, ANeSCR shall deliver to ABRC a report of expenditures by ANeSCR during such period of ABRC Funding previously disbursed by ABRC to ANeSCR in such period (“Quarterly Expenditure Reports”) meeting the requirements of Subsection 3.2.9, allocated among categories set forth in Subsection 5.1.

**3.2.8.4** Annual Report. Within ninety (90) Days after the close of each Fiscal Year of the State of Arizona (by October 1), ANeSCR shall deliver to ABRC an annual report

(“Annual Report”) containing a fair summary of the activities of ANeSCR for the year ended the preceding June 30, which shall include matters such as grants obtained, number of patients and researchers served, patents applied for and granted (if any), and abstracts and articles published in professional and peer reviewed journals or citations thereto.

**3.2.8.5** Extensions. ANeSCR may request an extension of the deadline for submission of any item required by Subsections 3.2.8.1 - 3.2.8.4 for a period not to exceed sixty (60) Days, provided that the Executive Director shall retain discretion to grant or deny such request, but no extension will be granted if such extension would cause ABRC to be delinquent in its own reporting obligations.

**3.2.9** Requirements for Expenditure Reports. The timing of required submittals of Expenditure Reports is set forth in Subsections 3.2.8.2 and 3.2.8.3. ANeSCR shall be deemed to have represented and warranted to ABRC in each Expenditure Report that (a) the report is not in any way inconsistent with any Expenditure Report prepared by ANeSCR for the source of any other funds provided to ANeSCR, except as may be specifically required by ABRC in this Agreement, (b) the report accurately and fairly represents all uses of ABRC Funding required to be reported during the period, and (c) the report complies with this Contract.

**3.2.9.1** Single Source Accounting Method. During the period as to which the Expenditure Report relates, if ANeSCR shall have maintained all ABRC Funding received during the period (“Current Period ABRC Funding”) in an account or accounts segregated from all other funds, the report of the expenditures of Current Period ABRC Funding shall include total expenditures by ANeSCR from such segregated accounts in each category of Allowable Expenditures shown in Subsection 5.1, and the total of all such categories, and ABRC audit and inspection rights shall apply only to funds disbursed from the segregated accounts.

**3.2.10** Insurance. ANeSCR shall maintain the insurance coverage required pursuant to Subsection 10.3.

**3.2.11** Antitrust Violations. Contractor/ANeSCR assigns to the State any claim for overcharges resulting from antitrust violations to the extent that those violations concern Materials or Services

supplied by third-parties to Contractor/ANeSCR for or toward fulfillment of this Contract.

**3.2.12** Board (Manager/Members)/ABRC Approvals of Annual Budgets and of Business Plans. On or before the sixtieth 60<sup>th</sup> day of each Contract Year of ANeSCR, the board of directors (or manager/members, if an L.L.C.) of ANeSCR will approve a budget for ANeSCR of revenues and expenses for the 12 months commencing July 1, including: pro forma balance sheets as of July 1 and the following June 30, pro forma statements of income and expenses, and sources and uses of funds statements for such 12-month period, and will approve a corresponding business plan for a period that includes such Contract Year. **Such approved budgets and business plans shall promptly be provided each year to ABRC for its review and written approval.**

**3.3** Warranty and Covenants of ABRC. ABRC warrants that it is authorized to enter into this Contract. Whenever, pursuant to this Contract, ABRC acts or exercises discretion, or makes a determination, including without limitation discretion to grant or deny requests for extensions under Subsection 3.2.8.5, the satisfaction of ABRC with Contractor's demonstration of Matching Funds under Subsection 4.1, requests for documentation of insurance under Subsection 10.3, and requests for evidence of diligent and continuous prosecution of cure under Subsection 14.1.1, it will do so in a manner that is not arbitrary or capricious within the meaning of A.R.S. § 12-910(E) and applicable judicial interpretations.

#### **4. ABRC DISBURSEMENTS AND CONTRACTOR MATCHING REQUIREMENT**

ABRC will disburse to Contractor/ANeSCR a total of \$5,000,000 over the period of 2008-2013 ("ABRC Funding Commitment"). As a condition of this disbursement, Contractor is required to provide Matching Funds on a 1:1 basis. Such Matching Funds may be any combination of Contractor's own funds, donated funds, and/or grant funds from other sources properly authorized for this purpose. In-kind matches may be accepted by ABRC when they are directly associated with ANeSCR requirements and offered for the disbursement period as required. Appropriate in-kind matching proposals may include such things as: joint use of existing space, joint use of existing information systems and other equipment, and joint use of existing personnel.

ABRC's annual disbursement in each of the five (5) Contract Years of this Contract shall match exactly the dollar (or in-kind dollar-equivalent) amount of Matching Funds provided by Contractor for each Contract Year, up to the total ABRC Funding Commitment. Such annual disbursements shall be used by

Contractor/ANeSCR for Allowable Expenditures (as defined in Section 5) provided that Contractor/ANeSCR is not in default hereunder and that all of the conditions herein have been satisfied. If Contractor/ANeSCR is in any manner in default in the performance of any obligation under this Contract, or if audit exceptions are identified, and if Contractor/ANeSCR does not cure such default or exception within the time required by Section 14, ABRC may, at its option and in addition to other available remedies, withhold disbursements that would otherwise be payable under this Section 4 until satisfactory resolution of the default or exception. Contractor/ANeSCR shall have the right to written notice of the reasons for ABRC's action in withholding payment. Under no circumstances shall ABRC authorize payments to Contractor/ANeSCR that exceed an amount specified in this Contract without an approved Contract Amendment. ABRC may, at its option, withhold final payment under this Contract until receipt of all final reports and deliverables required hereunder.

- 4.1 First Year and Subsequent Annual Disbursements. As a condition to ABRC's first Contract Year disbursement, ABRC must, within sixty (60) Days prior, be in receipt of Contractor/ANeSCR's Preliminary 5-Year Budget described in Subsection 3.1.5. ANeSCR's first-year budget requirements as shown therein shall serve to set the amount of ABRC's first Contract Year disbursement, as well as Contractor's Matching Funds requirement for that year. **Thereafter, subsequent years' ABRC disbursements and corresponding Contractor's Matching Funds requirements shall be set annually by ABRC based upon the annual budgets and business plans established and submitted to ABRC for review and approval pursuant to Subsection 3.2.12.**
- 4.2 Prior Year Requirements. No ABRC disbursement shall be made in any Contract Year unless (a) ABRC funds disbursed in the previous Contract Year have been duly expended or encumbered in their entirety, and (b) all requirements under this Contract then due for the preceding Contract Year have been satisfied.
- 4.3 Accounting for Unexpended and Unencumbered Amounts. ANeSCR must factor into the following year's budget requirements any portion of the funds disbursed by ABRC hereunder in any Contract Year that is unexpended or unencumbered at the end of that Contract Year, clearly identifying such funds as "carryover funds" and indicating the expected use of such funds in the following year's budget.
  - 4.3.1 Definitions of Encumbered Funds. For purposes of this Contract, funds shall be deemed encumbered during a Contract Year only for specific amounts and only if (a) a binding and enforceable obligation to pay such specific amount(s) has been incurred, or (b) funds have been allocated by ANeSCR to a dedicated account which has been created exclusively to fund a specific plan or program of Allowable Expenditures disclosed in writing to ABRC within sixty (60) Days of the beginning of any Contract

Year, provided that the amount so allocated is based on good-faith estimates by ANeSCR of the actual cost of the specified plan or program. To the extent that actual costs of a plan or program are less than such estimate, the excess funds will be deemed unencumbered as of the date when all actual costs of the plan or program become known to ANeSCR and are encumbered under (a) above. To the extent that ANeSCR's good-faith estimate of the actual costs of a plan or program are reduced, and ANeSCR elects to reduce the amount allocated to a dedicated account, the excess funds will be deemed unencumbered as of the date when ANeSCR notifies ABRC in writing of such reduced allocation. Increases in ANeSCR allocations to dedicated amounts above the levels disclosed to ABRC by September 1 of any year shall be treated as increases in encumbered amounts only upon approval by ABRC.

**4.3.2** Report of Encumbered Funds Not Expended by Following Year. Each July 1 during the term of this Contract, ANeSCR shall provide to ABRC a report of all ABRC Funding encumbered during one Contract Year that has not been expended on or before June 30 of the following Contract Year, and provide an explanation of how ANeSCR will factor such unexpended funds into the following year's budget.

**4.4** Specific Dates for All or Parts of ABRC's Annual Disbursements. The Parties agree to work together in good faith each year to establish a specific schedule for disbursing all or parts of each ABRC annual disbursement described in Subsection 4.1 consistent with the needs and requirements of ANeSCR as reflected in the annual budgets and business plans described in Subsection 3.2.12.

**4.5** Additional Prerequisites to Initial Disbursement of ABRC Funding. ABRC's initial disbursement is further conditioned upon satisfaction of the following conditions:

**4.5.1** Documentation of Funding Commitments. Delivery to ABRC by Contractor/ANeSCR of satisfactory documentation evidencing any and all funding commitments necessary to enable Contractor to meet its Matching Funds requirements under this Contract.

**4.5.2** Documentation of Nonprofit Incorporation & Tax-Exemption. Delivery to ABRC by Contractor/ANeSCR of copies of a certificate of good standing application for federal tax exempt status under 501(c)(3) of the Internal Revenue Code (or other suitable proof if exemption passed through to an L.L.C. by an existing nonprofit corporation), articles of incorporation (or articles of organization, if an L.L.C) showing the name of Contractor/ANeSCR as the Arizona Non-embryonic Stem Cell

Repository, current approved bylaws (or operating agreement, if an L.L.C), a resolution (authorized by the governing authority) ratifying Contractor/ANeSCR's execution of, and to-date performance under, this Contract, and a statement showing the title of the officer or officers authorized henceforth to execute reports under this Contract on behalf of Contractor/ANeSCR.

**4.5.3**     Documentation of Insurance Coverages. Delivery to ABRC of satisfactory evidence that the insurance required by Subsection 10.3 has been obtained.

**4.5.4**     No Events of Default. Contractor/ANeSCR shall not have caused an Event of Default, as defined in Section 14, and no event or failure to perform by Contractor/ANeSCR shall have occurred that, with notice or lapse of time or both, would constitute an Event of Default.

**4.6**       Authorized Funding Condition. Disbursements made by ABRC to Contractor/ANeSCR pursuant to this Contract are conditioned upon the continued availability to ABRC of funds authorized for expenditure in the manner and for the purpose herein. The State, including ABRC, shall not be liable for any purchases or subcontracts entered into by Contractor/ANeSCR in anticipation of such State monies not then available.

## **5.        ALLOWABLE EXPENDITURES**

**5.1**       Allowable Expenditures. Expenditure of ABRC funds disbursed pursuant to this Contract shall be made by Contractor/ANeSCR only for the following:

5.1.1      Reasonable salaries that are lawful for a 501(c)(3) organization such as ANeSCR. (Contractor/ANeSCR will provide to ABRC for its review and approval, prior to the first disbursement, and thereafter annually and at any time there are material changes, a copy of the ANeSCR compensation plan, including the job titles and classes and salary ranges for each title/class in the budget as approved by ANeSCR's board of directors (or manager/members, if an L.L.C.). This will include policies and procedures for administration of the compensation plan;

5.1.2      Other personnel costs that are lawful for a § 501(c)(3) organization such as ANeSCR and that are ordinary and customary;

5.1.3      Professional and outside services;

5.1.4      Capital equipment purchases, installation, and maintenance;



- 5.1.5 Supplies;
- 5.1.6 Travel, including personnel travel costs related to the establishment of ANeSCR. (Travel expenses not approved in the annual budget must be preapproved by ABRC);
- 5.1.7 Cell and tissue preparation and testing costs;
- 5.1.8 Patient care and education costs; and,
- 5.1.9 Costs of leasing space.

**5.2** Exclusions. Expenditures on the following items are expressly excluded from Allowable Expenditures:

- 5.2.1** Fines, Penalties. Any fine, sanction, or other penalty payable as a result of any payment by Contractor/ANeSCR, which is found to be unlawful.

**5.3** Advice Regarding Proposed Expenditures. If desired by Contractor/ANeSCR, Contractor/ANeSCR may seek written confirmation from ABRC that one or more proposed expenditures are Allowable Expenditures in the opinion of ABRC. ABRC shall give Contractor/ANeSCR notice of its determination within thirty (30) Days after submission by Contractor/ANeSCR of supporting documents. However, ABRC shall have no liability if a court of competent jurisdiction later makes a determination contrary to the determination of ABRC.

## **6. SUBCONTRACTS**

**6.1** No Subcontract Without Compliance With Conditions. The books, accounts, reports, files, and other records of any subcontractor that indirectly receives State funds under this Contract shall be subject to inspection, audit, and production to the extent required by A.R.S. §§ 35-214 (A), as amended, and 41-2548 (B), as amended. Contractor/ANeSCR shall not enter into a Subcontract with any other person or entity to perform any of the covenants of, or provide or account for any item required by, this Contract unless:

- 6.1.1** Conformity of Subcontracts. Contractor/ANeSCR uses a written Subcontract which (a) requires compliance with applicable Federal and State laws, and (b) contains provisions to the effect that the subcontractor agrees that ABRC and any other appropriate agent of the State, or any of their duly authorized representatives, shall, to the extent required by A.R.S. §§ 35-214

(A), as amended, and 41-2548 (B), as amended, or other applicable law, have access to the subcontractor's facilities and the right to examine any books, documents, and records of the subcontractor involving transactions related to the Subcontract, and that such books, documents, and records shall not be disposed of except as provided herein. Specifically, but without limitation, subcontractors shall preserve and make available records relating to this Contract as required by Subsection 9.5.

**6.1.2** Contractor/ANeSCR's Primary Responsibility and Liability. Contractor/ANeSCR shall at all times remain solely and exclusively responsible for meeting all terms, requirements, and obligations under this Contract, particularly including the requirements of Section 10 hereof, regardless of whether or not Subcontracts are used.

**6.1.3** Accounting Procedures. Contractor/ANeSCR shall maintain a system of accounting procedures and controls, which permit inspection, audit, and production of all Subcontracts to the extent required by A.R.S. §§ 35-214 (A), as amended, and 41-2548 (B), as amended.

## **7. PUBLICATION**

**7.1** Copies of Publications. Contractor/ANeSCR, its employees, and authorized agents shall provide ABRC with a copy of any manuscripts of proposed publications relating to matters for which funds under this Contract have been used at least thirty (30) days prior to any publication.

**7.2** Disclaimer. If ANeSCR chooses to state in any publication that its work has been funded in whole or in part by ABRC, ANeSCR shall include a disclaimer that the statements made in such publication are not made on behalf of ABRC, and have not been endorsed by ABRC.

## **8. CONFIDENTIALITY OF MEDICAL AND HEALTH RECORDS**

**8.1** Medical Records. ANeSCR shall establish and maintain written policies, procedures, and controls that comply with all applicable State statutes and regulations governing the use and disclosure of confidential medical information and records, including provisions that medical information, names, or other information regarding any person applying for, claiming, or receiving services funded by this Contract, or any employer of such person, shall not be made available for any political or commercial purpose. Information received from a federal or state agency, or from any person or provider acting under the federal or state agency pursuant to federal or state law, shall be disclosed only as provided by federal or state law.

- 8.2** HIPAA Compliance. ANeSCR shall also specifically comply with the Standards for Privacy of Protected Health Information (“PHI”) under the Health Insurance Portability and Accountability Act of 1996 contained in 45 CFR Parts 160 and 164 (the “HIPAA Privacy Standards”) and all other applicable federal privacy laws, as applicable.

**9. RECORDS, VISITATION, AUDIT, AND INSPECTION**

- 9.1** Access to Records. Contractor/ANeSCR agrees that ABRC and the State, or any of their duly authorized representatives, shall have access during business hours to Contractor/ANeSCR’s facilities and the right to examine Contractor/ANeSCR’s books, documents, and records involving transactions related to this Contract, including without limitation records relating to Subsection 5.1. hereof.
- 9.2** Statutory Financial Requirement. Contractor/ANeSCR shall comply with the certified financial and compliance audit provision of A.R.S. § 35-181.03, as amended, and shall be subject to audit as provided in A.R.S. §§ 35-214, as amended, 41-2548, as amended, and 41-1279.04, as amended.
- 9.3** Audits by State. The practices, procedures, and standards required by the General Accounting Office of the Arizona Department of Administration shall be used by ABRC or other agent of the State when performing any audit of this Contract.
- 9.4** Cost or Pricing Data. Contractor/ANeSCR shall maintain books and records which reflect cost or pricing data of the items paid for by ABRC Funding and which reflect the expenditures of ABRC Funding. All books and records relating to this Contract shall be maintained in accordance with generally accepted accounting principles (GAAP).
- 9.5** Preservation of Records. Subcontractors shall preserve and make available to ABRC and its auditors all records required hereunder for a period of five (5) years from their completion of the Subcontract. Contractor/ANeSCR shall preserve and make available to ABRC and its auditors all records required hereunder for a period of five (5) years from the date of final payment under this Contract, and for such period as is required by any other paragraph of this Contract, including the following:
- 9.5.1** If this Contract is completely or partially terminated, the records relating to the work terminated shall be preserved and made available for a period of five (5) years from the date of any such termination.
- 9.5.2** Records that relate to disputes, litigation, or settlement of claims arising out of the performance of this Contract, or to cost and

expenses of this Contract, to which exception has been taken by the Executive Director, shall be retained by Contractor/ANeSCR until such appeals, litigation, claims, or exceptions have been finally resolved.

- 9.5.3** If requested, Contractor/ANeSCR shall submit such records relating to the Contract to the Executive Director at the address herein specified.

## **10. INDEMNIFICATION AND INSURANCE**

**10.1** General Indemnification. Contractor/ANeSCR shall indemnify, defend, save, and hold harmless the State of Arizona, its departments, agencies, boards, commissions, universities and its officers, officials, agents, and employees (including ABRC, hereinafter referred to as "Indemnatee") from and against any and all claims, actions, liabilities, damages, losses, or expenses (including court costs, attorneys' fees, and costs of claim processing, investigation and litigation) (hereinafter referred to as ("Claims")) for bodily injury or personal injury (including death), or loss or damage to tangible or intangible property caused, or alleged to be caused, in whole or in part, by the negligent or willful acts or omissions of Contractor/ANeSCR or any of its owners, officers, directors, agents, employees or subcontractors. This indemnity includes any claim or amount arising out of or recovered under the Workers' Compensation Law or arising out of the failure of Contractor/ANeSCR to conform to any federal, state, or local law, statute, ordinance, rule, regulation or court decree. It is the specific intention of the Parties that the Indemnatee shall, in all instances, except for Claims arising solely from the negligent or willful acts or omissions of the Indemnatee, be indemnified by Contractor/ANeSCR from and against any and all claims. It is agreed that Contractor/ANeSCR will be responsible for primary loss investigation, defense, and judgment costs where this indemnification is applicable. In consideration of the award of this Contract, Contractor/ANeSCR agrees to waive all rights of subrogation against the State of Arizona, its officers, officials, agents and employees for losses arising from the work performed by Contractor/ANeSCR for the State of Arizona.

**10.2** Patent and Copyright Indemnification. Contractor/ANeSCR at its sole expense, shall defend any claim, action, or suit, which may be brought against the State of Arizona, its officers, officials, agents, and employees for the infringement of United States patents or copyrights arising from Contractor/ANeSCR's use of any equipment, materials, or information prepared or developed in connection with this Contract. In any such claim, action, or suit Contractor/ANeSCR shall satisfy any final judgment for such infringement. ABRC shall give Contractor/ANeSCR written notice of, and full information on, any such claim, action, or suit of which it becomes aware and shall cooperate with Contractor/ANeSCR in regard

thereto. ABRC may participate in the defense of any such claim, action, or suit at its sole discretion. However, if ABRC participates, it shall not assess its costs or expenses to Contractor/ANeSCR under this paragraph without Contractor/ANeSCR's written consent.

- 10.3 Insurance Requirements.** Contractor/ANeSCR and its subcontractors shall procure and maintain until all of their obligations have been discharged, including until any warranty periods under this Contract are satisfied, insurance against claims for injury to persons or damage to property which may arise from or in connection with the performance of the work hereunder by Contractor/ANeSCR, and its agents, representatives, employees or subcontractors.

The insurance requirements herein are minimum requirements for this Contract and in no way limit the indemnity covenants contained in this Contract. The State of Arizona in no way warrants that the minimum limits contained herein are sufficient to protect Contractor/ANeSCR from liabilities that might arise out of the performance of the work under this contract by Contractor/ANeSCR, its agents, representatives, employees or subcontractors, and Contractor/ANeSCR is free to purchase additional insurance.

- 10.3.1 Minimum Scope and Limits of Insurance.** Contractor/ANeSCR shall provide coverage with limits of liability not less than those stated below.

**1. Commercial General Liability – Occurrence Form**

- Each Occurrence  
\$1,000,000
  - General Aggregate  
\$2,000,000
  - Products – Completed Operations Aggregate  
\$1,000,000
  - Personal and Advertising Injury  
\$1,000,000
  - Blanket Contractual Liability – Written and Oral  
\$1,000,000
- a. The policy shall be endorsed to include the following additional insured language: **“The State of Arizona, Arizona Biomedical Research Commission shall be named as additional insured with respect to liability arising out of the activities performed by or on behalf of Contractor/ANeSCR.”**
- b. Policy shall contain a waiver of

subrogation against the State of  
Arizona, Arizona Biomedical Research  
Commission for losses arising from  
work performed by or on behalf of  
Contractor/ANeSCR.

## **2. Worker's Compensation and Employers' Liability**

Workers Compensation Coverage A: Statutory  
Employers Liability Coverage B:

Each Accident \$500,000  
Disease--Each Employee \$500,00  
Disease--Policy Limit \$1,000,000

- a. Policy shall contain a waiver of subrogation against the State of Arizona, Arizona Biomedical Research Commission for losses arising from work performed by or on behalf of Contractor/ANeSCR.
- b. This requirement shall not apply to: Separately, EACH contractor or subcontractor exempt under A.R.S. 23-901, AND when such contractor or subcontractor executes the appropriate waiver (Sole Proprietor/Independent Contractor) form.

## **3. Professional Liability (Errors and Omissions Liability)**

Each Claim - \$1,000,000  
Annual Aggregate - \$2,000,000

- a. In the event that the professional liability insurance required by this Contract is written on a claims-made basis, Contractor/ANeSCR warrants that any retroactive date under the policy shall precede the effective date of this Contract; and that either continuous coverage will be maintained or an extended discovery period will be exercised for a period of two (2) years beginning at the time work under this Contract is completed.
- b. The policy shall cover professional misconduct or lack of ordinary skill for those positions defined in the Scope of Work (i.e., Offeror Work Plan) of this Contract.

- 10.4 Additional Insurance Requirements.** The policies shall include, or be endorsed to include, the following provisions:
1. The State of Arizona, Arizona Biomedical Research Commission wherever additional insured status is required. Such additional insured shall be covered to the full limits of liability purchased by Contractor/ ANeSCR, even if those limits of liability are in excess of those required by this Contract.
  2. Contractor/ANeSCR 's insurance coverage shall be primary insurance with respect to all other available sources.
  3. Coverage provided by Contractor/ANeSCR shall not be limited to the liability assumed under the indemnification provisions of this Contract.
- 10.5 Notice of Cancellation.** Each insurance policy required by the insurance provisions of this Contract shall provide the required coverage and shall not be suspended, voided, canceled, or reduced in coverage or in limits except after thirty (30) days prior written notice has been given to the State of Arizona. Such notice shall be sent directly to Arizona Biomedical Research Commission, and shall be sent by certified mail, return receipt requested.
- 10.6 Acceptability of Insurers.** Insurance is to be placed with duly licensed or approved non-admitted insurers in the state of Arizona with an “A.M. Best” rating of not less than A-VII. The State of Arizona in no way warrants that the above-required minimum insurer rating is sufficient to protect Contractor/ANeSCR from potential insurer insolvency.
- 10.7 Verification of Coverage.** Contractor/ANeSCR shall furnish the State of Arizona with certificates of insurance (ACORD form or equivalent approved by the State of Arizona) as required by this Contract. The certificates for each insurance policy are to be signed by a person authorized by that insurer to bind coverage on its behalf.

All certificates and endorsements are to be received and approved by the State of Arizona before work commences. Each insurance policy required by this Contract must be in effect at or prior to commencement of work under this Contract and remain in effect for the duration of the project. Failure to maintain the insurance policies as required by this Contract, or to provide evidence of renewal, is a material breach of this Contract.

All certificates required by this Contract shall be sent directly to ABRC. The State of Arizona RFP/contract number and project description shall be noted on the certificate of insurance. The State of Arizona reserves the right to require complete, certified copies of all insurance policies required by this Contract at any time. **DO NOT SEND CERTIFICATES OF INSURANCE TO THE STATE OF ARIZONA'S RISK**

## **MANAGEMENT SECTION.**

- 10.8** Subcontractors. Contractor/ANeSCR's certificate(s) shall include all subcontractors as insureds under its policies **or** Contractor/ANeSCR shall furnish to the State of Arizona separate certificates and endorsements for each subcontractor. All coverages for subcontractors shall be subject to the minimum requirements identified above.
- 10.9** Approval. Any modification or variation from the insurance requirements in this Contract shall be made by the Department of Administration, Risk Management Section, whose decision shall be final. Such action will not require a formal Contract Amendment, but may be made by administrative action.
- 10.10** Exceptions. In the event the Contractor or sub-contractor(s) is/are a public entity, then the insurance requirements shall not apply. Such public entity shall provide a Certificate of Self-Insurance. If the Contractor or sub-contractor(s) is/are a State of Arizona agency, board, commission, or university, none of the above shall apply.

## **11. CONTRACT AMENDMENTS**

- 11.1** Contract Amendments. No condition, requirement, or alteration contained in or made a part of this Contract shall be waived or modified without a written Contract Amendment.
- 11.2** Request for Contract Amendments. Any request for a Contract Amendment shall be in writing, shall be delivered in person, courier, or U.S. mail, and shall be directed to the persons and addresses specified herein.

## **12. DISPUTES AND CONTRACT CLAIMS**

- 12.1** Good Faith. In the event of a dispute or claim under this Contract, the disputing Party agrees to advise the other Party in writing as to the basis of the dispute or claim, and to make a good faith attempt to resolve the dispute or claim prior to taking formal action.
- 12.2** Administrative Review of Contract Claims or Disputes. If the dispute or claim cannot be resolved pursuant to Subsection 12.1, it shall be resolved pursuant to A.R.S. Title 41, Chapter 23, Article 9, and the rules adopted thereunder.
- 12.3** Arbitration. After exhausting the applicable administrative review process and, to the extent required under A.R.S. §12-1518, as amended, the Parties agree to resolve all disputes or claims arising out of, or related to, this Contract through arbitration.



### **13. TERMINATION OF CONTRACT**

In addition to termination pursuant to Section 14, this Contract may be terminated under the following conditions.

- 13.1** Suspension. ABRC may terminate this Contract in whole or in part if, during the term of this Contract, Contractor/ANeSCR is listed on the master list of debarments, suspensions, and voluntary exclusions maintained pursuant to A.A.C. R2-7-C911, and/or is otherwise disapproved as a contractor or subcontractor of any public procurement unit or other governmental body. In such case, the Executive Director shall transmit written notice of termination to Contractor/ANeSCR by certified mail, return receipt requested, and this Contract shall be terminated effective upon receipt thereof by Contractor/ANeSCR or upon such later date as is specified in the notice.
- 13.2** Gratuities. ABRC may terminate this Contract by written notice to Contractor/ANeSCR if it is found by the Executive Director, after notice and opportunity for a hearing, that unlawful Gratuities were offered or given by Contractor/ANeSCR, or any agent or representative of Contractor/ANeSCR, to any officer or employee of the State with a view toward securing favorable treatment with respect to the awarding, amending, or making of any determinations with respect to the performance of, this Contract or any other public contract. The State, in addition to any other rights or remedies, shall be entitled to recover exemplary damages in the amount of three (3) times the value of the Gratuity offered by Contractor/ANeSCR.
- 13.3** Conflict of Interest. Pursuant to A.R.S. § 38-511, ABRC may cancel this Contract within three (3) years after Contract execution without penalty or further obligation by ABRC if any person significantly involved in initiating, negotiating, securing, drafting, or creating this Contract on behalf of ABRC is, or becomes at any time while the Contract or any extension of the Contract is in effect, an employee, agent, or consultant of Contractor/ANeSCR in any capacity with respect to the subject matter of this Contract. Cancellation under this Subsection shall be effective when written notice from ABRC is received by Contractor/ANeSCR, unless the notice specifies a later time. In addition to the right to cancel this Contract as provided in this Subsection, ABRC may recoup any fee or commission paid or due to any person significantly involved in initiating, negotiating, securing, drafting, or creating this Contract on behalf of ABRC from Contractor/ANeSCR.
- 13.4** Mutual Consent. This Contract may be terminated by mutual written consent of the Parties, specifying the termination date therein.
- 13.5** No Appropriations. If State monies are not made available to support

continuation of performance of this Contract in a subsequent fiscal period, this Contract may be canceled by ABRC without any further obligation upon ABRC or the State.

- 13.6** Default. This Contract may be terminated by ABRC or Contractor/ANeSCR upon sixty (60) Days written notice to the other if there is an Event of Default by the other, which is uncured as provided in Section 14.

## **14. DEFAULT**

- 14.1** Events of Default. The existence or occurrence of any one or more of the following events shall constitute an Event of Default under this Contract:

**14.1.1** Default. Material failure by Contractor/ANeSCR or ABRC in the observance or performance of any of the terms, covenants, agreements, or conditions contained in this Contract for a period of thirty (30) Days after notice thereof; provided, however, that if such default is not curable by the payment of money and cannot reasonably be cured within thirty (30) Days (but is reasonably susceptible of cure), no Event of Default shall occur hereunder so long as the defaulting Party commences such cure within the thirty (30) day period and thereafter diligently and continuously prosecutes same to completion (and satisfies requests of ABRC for evidence of diligent and continuous prosecution of cure) and continues to perform all of its other obligations hereunder during such period.

**14.1.2** Insurance. Contractor/ANeSCR's failure to maintain the insurance coverage required pursuant to Section 10 for the duration of this Contract, unless any such failure or lapse is cured without actual prejudice to ABRC within five (5) business days from lapse of coverage.

**14.1.3** Misrepresentation. The existence of any material mistake or misrepresentation of fact by Contractor/ANeSCR in any document submitted to ABRC pursuant to this Contract, or otherwise in connection with the ABRC Funding, which, in ABRC's reasonable judgment, causes or may cause material harm to ABRC or the State and which, if susceptible to cure, is not promptly cured upon written notice to Contractor/ANeSCR.

**14.1.4** Tax-Exempt Status; Legislative Criteria. ANeSCR loses its status as an Arizona nonprofit corporation (or nonprofit L.L.C., as the case may be), tax-exempt under I.R.S. Section 501(c)(3), or is no longer providing "centralized public Arizona repositories of diverse types of human stem cells of non-embryonic origin for public use," as specified in the authorizing legislation.

- 14.1.5** Insolvency. The inability of Contractor/ANeSCR to pay its debts when due; or the existence of a general assignment made by Contractor/ANeSCR for the benefit of its creditors; or the filing by or against Contractor/ANeSCR of a voluntary or involuntary petition in bankruptcy; or the appointment of a receiver, or the commencement under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors, of proceedings for the composition, extension, arrangement, or adjustment of any of Contractor/ANeSCR's obligations hereunder (unless any of the foregoing are promptly dismissed or resolved); or the suspension or discontinuance of Contractor/ANeSCR's business.
- 14.1.6** Other Default. A default by Contractor/ANeSCR on any other material obligation it may have to ABRC which, if susceptible to cure, is not promptly cured upon written notice to Contractor/ANeSCR; or the issuance or levy of a writ of attachment, execution, or any similar process against any significant part of Contractor/ANeSCR's property that is not released, stayed, bonded, or vacated within a reasonable time after its issue or levy.
- 14.1.7** Violation of Law. (a) Contractor/ANeSCR's failure to cure promptly any material violation of any law or regulation, or Contractor/ANeSCR's failure to comply promptly with any provision of any material notice, issued by or filed in any department of any governmental authority having jurisdiction over Contractor/ANeSCR; or, (b) Contractor/ANeSCR's failure to furnish to ABRC, immediately and without demand, a true copy of any notice or other document received by, or available to, Contractor/ANeSCR disclosing any such requirement or violation of any such law or regulation.
- 14.2** Remedies. If Contractor/ANeSCR is the defaulting Party, ABRC may cease disbursements under this Contract, with or without terminating this Contract, and take all steps necessary to recoup any ABRC Funding not expended or encumbered for Allowable Expenditures. Otherwise, in the event of any Event of Default, the non-defaulting Party may (i) terminate this Contract upon written notice to the other Party, and (ii) to the extent permitted by law and not prohibited by Section 12, take whatever action at law or in equity as may appear necessary or desirable. In the event this Contract is terminated, ABRC shall, notwithstanding such event, remain committed for, and Contractor/ANeSCR shall retain, those funds that were expended or duly encumbered for Allowable Expenditures during the time in which this Contract was in effect and there was not an Event of Default. ABRC shall have no liability for, or in connection with, any amount expended or encumbered by Contractor/ANeSCR, regardless of whether for an Allowable Expenditure, after it has served notice upon Contractor/

ANeSCR of an Event of Default (provided that ABRC shall resume disbursements if all Events of Default are subsequently cured as provided herein).

**14.2.1** ABRC's Right to Assurance. If ABRC in good faith has reason to believe that Contractor/ANeSCR does not intend, or is unable, to perform or continue performing under this Contract, ABRC may demand in writing that Contractor/ANeSCR give a written assurance of intent to perform. Failure by Contractor/ANeSCR to provide written assurance within the number of Days specified in the demand may, at ABRC's option, be the basis for ABRC terminating this Contract, or exercising its other rights and remedies available by law or provided by this Contract.

**14.3** Attorneys' Fees and Other Expenses. If any legal action becomes necessary pursuant to this Contract, reasonable attorneys' fees and other expenses as may be fixed and awarded by the Court in accordance with A.R.S. §§ 12-341.01 and 12-348 may be obtained by the successful Party.

**14.4** Acceptance of Legal Process.

14.4.1 In the event that any legal action is commenced by Contractor/ANeSCR against ABRC, service of process on ABRC shall be made by personal service upon the Executive Director, or in such other manner as may be provided by law.

14.4.2 In the event that any legal action is commenced by ABRC against Contractor/ANeSCR, service of process shall be made by personal service upon the signatory hereto, or in such other manner as may be provided by law, whether made within or without the State of Arizona.

**14.5** Rights and Remedies Are Cumulative. Except as otherwise expressly stated in this Contract, the rights and remedies of the Parties are cumulative, and the exercise of one or more of a Party's rights or remedies shall not preclude the exercise by it, at the same time or at different times, of any other rights or remedies provided herein, or under applicable law, for the same Event of Default or any other Event of Default.

**14.6** Substitute Performance. In the event ABRC terminates this Contract in whole or in part as provided in this Subsection, ABRC may procure, upon such terms and in such manner as it deems appropriate, Services similar to those so terminated.

## **15. STATE EXECUTIVE ORDERS & OTHER LEGAL REQUIREMENTS**

Contractor/ANeSCR agrees at all times to comply with the requirements of the

following State Executive Orders and other indicated legal requirements.

**15.1** Non-Discrimination. Contractor acknowledges that it has read and understands the requirements of State Executive Order No. 99-4 (which is incorporated herein by this reference), and A.R.S. §§ 41-1461 *et seq.*, both of which mandate certain actions by entities contracting with the State of Arizona to ensure that all persons, regardless of race, color, religion, sex, age, disability, or national origin, shall have equal access to employment opportunities. Contractor/ANeSCR also shall comply with all other applicable federal and State employment laws, rules, and regulations. Contractor/ANeSCR shall take affirmative action to ensure that applicants for employment and employees are not discriminated against due to race, color, religion, sex, age, disability, or national origin in activities including but not limited to the following: employment, upgrading, demotion, transfer, recruitment or recruitment advertising, layoff or termination, rates of pay or other forms of compensation, and/or selection for training, including apprenticeships. Contractor/ANeSCR further agrees that this provision will be incorporated into all Subcontracts utilizing ABRC funds.

**15.2** Offshore Work Prohibition. Due to security and identity protection concerns, direct Services under this Contract shall be performed within the borders of the United States. Any Services that are described in the specifications or Work Plan that directly serve the State of Arizona or its clients, and may involve access to secure or sensitive data or personal client data or development or modification of software for the State, shall be performed within the borders of the United States. Unless specifically stated otherwise elsewhere in this Contract, this definition does not apply to indirect or “overhead” Services, redundant back-up Services, or Services that are incidental to the performance of this Contract. This provision applies to work performed by subcontractors at all tiers.

**15.3** Federal Immigration Laws. Contractor acknowledges that it has read and understands the requirements of State Executive Order No. 2005-30 (which is incorporated herein by this reference). By entering into this Contract, Contractor warrants compliance with the Federal Immigration and Nationality Act (FINA) and all other Federal immigration laws and regulations related to the immigration status of its employees. Contractor/ANeSCR shall obtain statements from its subcontractors certifying their compliance and shall furnish the statements to ABRC upon request. These warranties shall remain in effect through the term of this Contract. Contractor/ANeSCR and its subcontractors shall also maintain Employment Eligibility Verification forms (I-9) as required by the U.S. Department of Labor’s Immigration and Control Act, for all employees performing work under this Contract. (I-9 forms are available for download at USCIS.GOV.)

ABRC may request verification of compliance from Contractor/ANeSCR or any subcontractor performing work under this Contract. Should ABRC

suspect or find that Contractor/ANeSCR or any of its subcontractors are not in compliance, ABRC may pursue any and all remedies allowed by law, including but not limited to: suspension of work, termination of the Contract for default, and suspension and/or debarment of Contractor/ANeSCR. All costs necessary to verify compliance are the responsibility of Contractor/ANeSCR.

**15.4** Pandemic Contractual Performance. Contractor/ANeSCR shall provide a written plan that illustrates how Contractor/ANeSCR shall perform up to Contractual standards in the event of a pandemic. ABRC may require a copy of the plan at anytime prior or post award of this Contract. At a minimum, the pandemic performance plan shall include:

- (i) Key succession and performance planning if there is a sudden significant decrease in Contractor/ANeSCR's workforce.
- (ii) Alternative methods to ensure there are products in the supply chain.
- (iii) An up to date list of company contacts and an organizational chart.

In the event of a pandemic, as declared by the Governor of Arizona, U.S. Government, or the World Health Organization, which makes performance of any term under this Contract impossible or impracticable, the State shall have the following rights:

- (i) After the official declaration of a pandemic, the State may temporarily void this Contract, in whole or specific sections, if Contractor/ANeSCR cannot perform to the standards agreed upon in the initial terms.
- (ii) The State shall not incur any liability if a pandemic is declared and emergency procurements are authorized by the Director of the Department of Administration as per A.R.S. § 41-2537 of the Arizona Procurement Code.
- (iii) Once the pandemic is officially declared over and/or Contractor/ANeSCR can demonstrate its ability to perform, the State, at its sole discretion, may reinstate this temporarily voided Contract.

**15.5** Drug Free Work Place Act. Contractor/ANeSCR shall, and shall by contract require any party with which it has a Subcontract to, abide by all applicable provisions of the Drug Free Work Place Act and all rules and regulations promulgated thereunder.

**15.6** Implied Contract Terms. Each provision of law and any terms required by law to be in this Contract are a part of this Contract as if fully stated herein.

## **16. RECOUPMENT OF CONTRACT PAYMENTS**

**16.1** Unacceptable Expenditures. Contractor/ANeSCR shall reimburse ABRC for all ABRC funds expended, which are determined by the dispute resolution process provided in Section 12 not to have been expended by Contractor/ANeSCR in accordance with the terms of this Contract.

**16.2** Refunds. Contractor/ANeSCR shall, within forty-five (45) Days of termination of this Contract, refund all amounts disbursed by ABRC and not expended on Allowable Expenditures, or committed for such expenditures pursuant to binding and enforceable agreements, on the date of termination.

## **17. PUBLIC RECORDS**

Any other provision of this Contract to the contrary notwithstanding, the Parties acknowledge that ABRC is a public body, and as such is subject to applicable provisions of the Arizona Public Records Act, i.e., A.R.S. §§ 39-121 to 39-121.03. Any provision of this Contract regarding confidentiality of records possessed by ABRC is limited to the extent necessary to comply with the provisions of State law. ABRC agrees to keep confidential any and all information and/or documents designated as confidential or proprietary by Offeror or Contractor/ANeSCR to the fullest extent permitted by law, including A.R.S. § 15-1640. In the event a public records request is made for information and/or documents designated as confidential or proprietary by Offeror or Contractor/ANeSCR, ABRC will notify same as soon as possible.

## **18. ASSIGNMENT**

Contractor/ANeSCR's rights or obligations under this Contract shall not be assigned without the prior written consent of ABRC. Contractor/ANeSCR acknowledges that the identity of ANeSCR and the structure and composition of its corporation (or L.L.C.) and board (or manager/member(s)) is of particular concern to ABRC, and that it is because of such structure, identity, and governing body composition that ABRC is entering into this Contract. Accordingly, a material change in ANeSCR as defined in Subsections 3.2.1 – 3.2.4 is a prohibited assignment of the rights and responsibilities set forth in this Contract. In the event of any prohibited assignment, no voluntary or involuntary assignee or successor in interest of Contractor/ANeSCR shall acquire any rights or powers under this Contract.

**19. GOVERNING LAW**

This Contract is governed by the laws of the State of Arizona including, where applicable, the Uniform Commercial Code as adopted by the State of Arizona and the Arizona Procurement Code (A.R.S. Title 41, Chapter 23) and the Arizona Procurement Code Rules and Regulations (A.C.C. Title 2, Chapter 7). Subject to the requirements of Subsections 12.1 -- 12.3, any legal action thereupon shall be initiated in the State of Arizona.

**20. REPRESENTATIVES; NOTICES, DEMANDS, AND COMMUNICATIONS BETWEEN THE PARTIES**

**20.1** Representatives. The Parties designate the following individuals, or such alternate representatives as may be identified in writing to the other Party, as their respective representatives for the purpose of coordination and communication under this Contract:

ABRC Representative: Executive Director of ABRC

Contractor Representative: \_\_\_\_\_

**20.2** Notices. All notices, demands, requests for approvals, consents, Contract Amendments, or other writings provided in this Contract to be given, made, or sent by either Party to the other, shall be deemed to have been fully given, made, or sent when made in writing and personally delivered, transmitted by telefax, or received by United States overnight delivery service operated by a recognized national courier, return receipt requested and addressed as follows:

To ABRC:

Executive Director  
Arizona Biomedical Research Commission  
15 S. 15<sup>th</sup> Ave., Suite 103-A  
Phoenix, Arizona 85007  
Fax: (602) 542-6380

and

Chairman  
Arizona Biomedical Research Commission  
15 S. 15<sup>th</sup> Ave., Suite 103-A  
Phoenix, Arizona 85007  
Fax: (602) 542-6380



and

Terry L. Corbett  
Assistant Attorney General  
Education and Health Section  
Office of the Attorney General  
1275 West Washington  
Phoenix, Arizona 85007  
Fax: (602) 364-0700

To Contractor:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

and

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

The address to which any notice, demand or other writing may be given, made, or sent to either Party may be changed by written notice given by such Party as above provided.

## **21. APPROVALS**

Wherever this Contract requires a Party to approve any contract, document, plan, proposal, specification, drawing, or other matter, it shall be delivered to the attention of the Party's Representative. Approvals shall not be unreasonably withheld or delayed.

## **22. GENERAL PROVISIONS**

**22.1** Nonliability of ABRC Officials, Agents, and Employees. No member, official, agent, or employee of ABRC shall be personally liable to Contractor/ANeSCR, or any successor in interest, in the event of any default or breach by ABRC, or for any amount which may become due to

Contractor/ANeSCR or successor, or for any obligation of ABRC under the terms of this Contract.

- 22.2** Enforced Delay: Extension of Time of Performance. In addition to specific provisions of this Contract, neither Party hereto shall be deemed to be in default where delays or defaults in performance are due to: causes that are unanticipated and beyond its control, such as war, insurrection, strikes, lock-outs, riots, floods, earthquakes, fires, casualties, acts of God, acts of the public enemy, epidemics, quarantine restrictions, freight embargoes, lack of transportation, governmental acts, restrictions or priority, litigation, unusually severe weather, or acts of the other Party. An extension of time for any such cause shall only be for the period of the enforced delay, which period shall commence to run from the time of the commencement of the cause. If, however, notice by the Party claiming such extension is sent to the other Party more than thirty (30) Days after the commencement of the cause, the period shall commence to run only thirty (30) Days prior to the giving of such notice. Times of performance under this Contract may also be extended in writing by the other Party hereto.
- 22.3** Severability. If any provision of this Contract shall be found invalid or unenforceable by a court of competent jurisdiction, the remaining provisions of this Contract which reasonably can be given effect apart from that which is invalidated, shall not be affected thereby and shall be valid and enforceable to the fullest extent permitted by law.
- 22.4** Captions. The captions contained in this Contract are merely a reference and are not to be used to construe or limit the text.
- 22.5** Entire Agreement. This Contract constitutes the entire understanding and agreement of the Parties. This Contract integrates all of the terms and conditions mentioned herein or incidental hereto, and supersedes all negotiations or previous contracts between the Parties with respect to all or any part of the subject matter hereof. No course of prior dealings between the Parties, and no usage of the trade, shall supplement or explain any terms used in this Contract and no other understanding, either oral or in writing, shall be binding.
- 22.6** No Third Party Beneficiaries. This Contract is for the benefit of and enforceable by only ABRC and Contractor/ANeSCR, and their respective successors and permitted assigns, if any, and shall not be deemed to have created any rights in any other parties, as third party beneficiaries or otherwise.
- 22.7** No Waiver. Except as otherwise specifically provided herein, no failure or delay by either Party in asserting any of its rights or remedies as to any default shall operate as a waiver of any default, or of any such rights or remedies, or deprive the Party of its right to institute and maintain any

actions or proceedings which it may deem necessary to protect, assert, or enforce any such rights or remedies.

**22.8** Counterparts. This Contract may be executed in multiple counterparts, each of which shall be deemed to be an original and all of which together shall be deemed to be one and the same instrument.

**EXECUTED THIS** \_\_\_\_\_ **DAY OF** \_\_\_\_\_, 200\_\_\_\_.

**ARIZONA BIOMEDICAL RESEARCH COMMISSION**

By: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

**CONTRACTOR:**

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

By: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

ATTACHMENT 1

Offeror's Attestation and Commitment Statement

RFP NO. FY08-200

**THE ARIZONA NON-EMBRYONIC STEM CELL REPOSITORY**

State of Arizona

County of Maricopa

\_\_\_\_\_ (“Offeror”), being first duly sworn upon their oath, hereby promises and asserts:

1. that they have fully read the entirety of this document, including the RFP and Funding Agreement portions, and completely understand all of the terms and conditions to which they will be legally bound if awarded a contract under this RFP;
2. that submission of their proposal did not include collusion or other anti-competitive practices;
3. that they have not been debarred, suspended, or otherwise lawfully prohibited from participating in any public procurement activity, including but not limited to being disapproved as a contractor or subcontractor of any public procurement unit or other governmental body;
4. that, if awarded a contract under this RFP, they will: incorporate a separate Arizona nonprofit corporation (or form a wholly-owned nonprofit L.L.C. if Offeror/Contractor is an existing Arizona nonprofit corporation), name it the “Arizona Non-embryonic Stem Cell Repository” (ANeSCR), apply for 501(c)(3) tax-exemption (unless such tax-exemption can be “passed through” to a wholly-owned L.L.C. by an existing Arizona nonprofit corporation), take all steps necessary to allow ANeSCR to succeed to Contractor’s interest in the awarded contract, and otherwise meet the ongoing organizational and other requirements for ANeSCR as described throughout this document; and,
5. that they have had full opportunity to review and discuss the entirety of this document and its requirements with counsel of their choosing.

Signed for Offeror by:\_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Subscribed and sworn to before me this \_\_\_\_\_day of \_\_\_\_\_,  
200\_\_.

(Seal and expiration date)

Notary Public